1807

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	
R. BRUCE WALLACE	
Serial No. 07/996,771	Group Art Unit 1807
Filed: December 24, 1992	Examiner: ~~S. Chambers~~ Parr
FOR: LIGATION AMPLIFICATION OF NUCLEIC ACID SEQUENCES	

TRANSMITTAL LETTER

Honorable Commissioner of
Patents and Trademarks
Washington, D. C. 20231

Sir:

Enclosed for filing in the subject application are:

1. Request Pursuant to 37 C.F.R. §1.607 for Interference Between This Application and Patent 4,988,167.

2. Declaration Pursuant to 37 C.F.R. §1.608.

Any fee due should be charged to Deposit Account 09-0948. A duplicate is attached.

Edward S. Irons
Registration No. 16,541
555 - 13th Street, N. W.
Suite 701 East Tower
Washington, D. C. 20004
(202) 626-3564

Dated: January 24, 1994

#11 B. White 2-3-94

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	
R. BRUCE WALLACE	:	
Serial No. 07/996,771	:	Group Art Unit 1807
Filed: December 24, 1992	:	Examiner: S. Chambers
FOR: LIGATION AMPLIFICATION OF NUCLEIC ACID SEQUENCES	:	

REQUEST PURSUANT TO 37 C.F.R. §1.607 FOR INTERFERENCE BETWEEN THIS APPLICATION AND PATENT 4,988,167

To 18Y 2-4-94 MP

Honorable Commissioner of
Patents and Trademarks
Washington, D. C. 20231

Sir:

Pursuant to 37 C.F.R. §1.607, applicant requests an interference between this application and United States patent 4,988,617.

Compliance with 37 C.F.R. §1.607(a)

(1) Patent 4,988,617 (filed March 25, 1988).

(2) Proposed Count:

The following proposed counts A, B and C are based on Claims 1, 18 and 19 of patent 4,988,617. Words deleted from the patent claims are indicated by brackets []. Words added to the patent claims are underlined.

Count A (Proposed). An assay for a biologically derived [denatured] DNA or RNA test substance, which has a known normal nucleotide sequence and a known possible mutation at at least one target nucleotide position in said sequence, which assay determines whether the test substance has said normal nucleotide sequence or said possible mutation, said assay comprising the steps of

(a) annealing a target oligonucleotide probe of predetermined sequence to a first sequence of said test substance so that said target nucleotide position is aligned with a nucleotide in an end region of said target probe,

(b) annealing an adjacent oligonucleotide probe of predetermined sequence to a second sequence of said test substance contiguous to said first sequence, so that the terminal nucleotide in said end region of said target probe and one end of said adjacent probe are directly adjacent to each other,

(c) contacting said annealed target probe and adjacent probe with a [linking agent] <u>ligase</u> under conditions such that the directly adjacent ends of said probes [covalently bond] <u>ligate</u> to form a linked probe product unless there is nucleotide base pair mismatching between said target probe and said test substance at the target nucleotide position,

(d) separating said test substance and linked probe product, if formed, and

(e) detecting whether or not said probe product is formed as an indication of nucleotide base pair matching or mismatching at said target nucleotide position.

Count B (Proposed). The assay of [claim 1] Count A wherein said test substance comprises DNA sequences derived from genomic DNA.

Count C (Proposed). The assay of [claim 18] Count B wherein said DNA sequences include sequences encoding all or part of normal ß-globin or sickle ß-globin gene.

(3) Patent claims 1, 18 and 19 correspond substantially to proposed Counts A, B and C.

(4) The Amendment filed January 12, 1994 presents claims 48, 49 and 50 which correspond exactly to proposed Counts A, B and C.

(5) This application is a continuation-in-part of application Serial No. 07/870,221 filed April 20, 1992 (abandoned; continuation application Serial No. 08/077,961 filed June 18, 1993 pending), which is a continuation of application Serial No. 07/178,377 filed April 6, 1988 (abandoned).

The terms of proposed Counts A, B and C (application claims 48, 49 and 50) are applied to application Serial No. 07/178,377.

(i) Preliminary Statement

Each of patent 4,988,617 and application Serial No. 07/178,377 describes a method or assay useful, for example, to identify a point mutation in a nucleic acid sequence by a template dependent ligation procedure. Both the patent and the application exemplify the invention by its use to detect normal and sickle cell β-globin genes. See, e.g., patent 4,988,617, Example 1 (Col. 13, l. 25) and application Serial No. 07/178,377, Example 5.

(ii) Specific application of proposed Count A (claim 48) to application Serial No. 07/178,377:

Count A (Claim 48)

Proposed Count A states:

> An assay for a biologically derived [denatured] DNA or RNA test substance, which has a known normal nucleotide sequence and a known possible mutation at at least one target nucleotide position in said sequence, which assay determines whether the test substance has said normal nucleotide sequence or said possible mutation, said assay comprising the steps of
>
> (a) annealing a target oligonucleotide probe of predetermined sequence to a first sequence of said test substance so that said target nucleotide position is aligned with a nucleotide in an end region of said target probe,
>
> (b) annealing an adjacent oligonucleotide probe of predetermined sequence to a second sequence of said test substance contiguous to said first sequence, so that the terminal nucleotide in said end region of said target probe and one end of said adjacent probe are directly adjacent to each other,

(c) contacting said annealed target probe and adjacent probe with a [linking agent] ligase under conditions such that the directly adjacent ends of said probes [covalently bond] ligate to form a linked probe product unless there is nucleotide base pair mismatching between said target probe and said test substance at the target nucleotide position,

(d) separating said test substance and linked probe product, if formed, and

(e) detecting whether or not said probe product is formed as an indication of nucleotide base pair matching or mismatching at said target nucleotide position.

Serial No. 07/178,377

It is believed apparent from inspection that each and every limitation of proposed Count A is exemplified by working examples 4, 5 and 6 of Serial No. 07/178,377.

See also claim 1 of application Serial No. 07/178,377.

Note that claim 2 is specific to DNA; whereas, claim 3 is specific to RNA.

Count B (Claim 49)

Proposed Count B states:

> The assay of [claim 1] Count A wherein said test substance comprises DNA sequences derived from genomic DNA.

Serial No. 07/178,377

Note that Example 5 of Serial No. 07/178,377 describes the application of the invention to genomic DNA.

Count C (Claim 50)

Proposed Count C states:

> The assay of [claim 18] Count B wherein said DNA sequences include sequences encoding all or part of normal β-globin or sickle β-globin gene.

Serial No. 07/178,377

See Examples 4, 5 and 6 of Serial No. 07/178,377.

Compliance with 37 C.F.R. §1.608(a)

The filing date of patent 4,988,617 is March 25, 1988. The effective filing date of the claims proposed as Counts A, B and C is the April 6, 1988 filing date of Serial No. 07/178,377.

Referring to 37 C.F.R. §1.608, it is clear that the effective filing date of this application is the filing date of Serial No. 07/178,377 which is less than one month after the filing date of patent 4,988,617.

A declaration alleging that there is a basis upon which applicant is entitled to a judgment relative to the patentee is attached hereto and marked Exhibit A.

Edward S. Irons
Registration No. 16,541
555 - 13th Street, N. W.
Suite 701 East Tower
Washington, D. C. 20004
(202) 626-3564

Dated: 1/7/94